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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,358	05/30/2001	Chong Jin Oon	20781-703	8357

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/870,358	OON ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22,26,27 and 43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22,26,27 and 43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed October 15, 2004. Currently, Claims 22, 26-27, 43-46 are pending.

2. Any objection or rejection not reiterated herein, has been withdrawn in view of the amendments to the claims or cancellation of the claims.

3. This action is made FINAL.

4. Any objections and rejections not reiterated below are hereby withdrawn.

Priority

5. This application claims priority to foreign application Singapore 20004041-0, filed July 18, 2000. A certified copy of the application has been provided.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 22, 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger et al. (Viral Hepatitis and Liver Disease, pages 138-143, Torino, Edizioni Minerva Medica, 1997) in view of Mbayed et al. (J. Clinical Microbiology, Vol. 36, No. 11, pages 3362-3365, November 1998) and further in view of either Yoshida et al. (Liver, Vol. 20, pages 411-414, October 2000) or Oon et al. (Antiviral Research, Vol. 41, pages 113-118, April 1999).

Weinberger et al. (herein referred to as Weinberger) teaches a method of amplification and detection of HBV DNA. Viral DNA was isolated from serum. Primer sequences, which represent highly conserved regions of the s-gene (Table 1) were added to the template DNA. Both the first and second round amplification comprised an initial denaturation step. The amplification was detected and visualized on agarose gels (page 139, col. 1). Sequence analysis of isolates from 14 patients with isolated anti-HBc reactivity are illustrated (page 140). The Table lists the detection of N131T (a

mutation at amino acid position 131). Weinberger teaches using primers which span the region comprising the nucleic acid encoding amino acid position 131. Therefore, Weinberger has determined whether the amplified products contain a mutation at amino acid position 131.

Weinberger does not specifically teach using primers of SEQ ID NO: 1 and 2. Weinberger further does not specifically teach that each mutation at 130, 131, 133 and 145 are mutations which may be used to detect a sample contains HBV that has escaped immunological detection of HbsAG.

However, Mbayed et al. teaches a method for detecting HBV nucleic acid target sequence in a sample, namely serum samples by amplifying the DNA using a nested PCR method to amplify part of the surface gene (page 3362, col. 2)(limitations of Claim 1). The extracted DNA was amplified with primers and then a second round of primer including primers HBS1 and HBS2. The HBS1 primer is 20 nucleotides in length. SEQ ID NO: 1 of the instant application comprises each of the 20 nucleotides of HBS1 with an additional T nucleotide on the 3' end. HBS2 is immediately downstream of SEQ ID NO: 2 of the instant application, namely four nucleotides downstream at 694-713. As seen in Figure 1, SEQ ID NO: 2 is positions 668-690 of the Figure. These nucleotide positions are conserved among the Gualeguay HBV isolates. The amplification product was sequenced as a means of detection. Mbayed teaches phylogenetic analysis shows "a clear different between the genotype distribution in Buenos Aires, a low-prevalence area, and that found in Gualeguay, Entre Rios, a high prevalence area" (abstract).

Yoshida teaches de novo acute hepatitis B infection in a previously vaccinated liver transplant recipient due to a strain of HBV with a Met133Thr mutation in the "a" determinant. Yoshida teaches that the HBV strain revealed mutations in the "a" determinant: Met133Thr and Asn131Thr. There two mutations were within the HBV surface antigen "a" determinant. Thus, Yoshida teaches that the 131 variant is present in a patient which has escaped immunological detection.

Oon teaches HBV variants with lamivudine-related mutations in the DNA polymerase and the 'a' epitope of the surface antigen. Oon teaches that analysis of the coding sequence covering the 'a' epitope indicated a mixture ot wild-type and mutant sequences, in which a novel mutation GGC to GAC leading to Gly130-Asp130 (GGC-GAC) in HbsAg was detected (page 1 15, col. 2, last lines). As seen in Table 1, clones 6-9 comprise an Asp at position 130 (page 1 16). Therefore, Clones 6-9 comprised an isolated nucleic acid HBV variant encoding the major HBV surface antigen that comprises a mutation at 130 from glycine to aspadic acid (G130D). The HBV also comprised a mutation at 145 from glycine to arginine (G145R).

The ordinary artisan would have been motivated to have detected multiple mutations which indicate that a sample may contain HBV that may have escaped immunological detection of HbsAg simultaneously. The art teaches that numerous mutations within the 'a' determinant indicate that an individual who has been vaccinated may still become infected with HBV, the ordinary artisan would have been motivated to have detected the samples for these mutations. The ordinary artisan would have been motivated to have amplified using SEQ ID NO: 1 and 2 since the claimed

oligonucleotides, namely SEQ ID NO: 1 and 2, simply represent functional equivalents to the primers taught in the art by Mbayed, the skilled artisan would have been motivated to have designed additional primers which amplified HBV nucleic acids. Given the teachings of Weinberger as to the location of mutations of interest in the HBV genome and Mbayed aligning HBV isolates, the ordinary artisan would have recognized alternative primers which are also within conserved regions of the HBV nucleic acids would be equivalents to the HBS1 and HBS2 primers. The skill in the art at the time the invention was made was very high with respect to designing species or isolate specific primers and for using PCR to amplify regions known to contain mutations. Therefore, the ordinary artisan would have recognized that designing primers which flank a mutation, to further sequence and detect the mutation would have been obvious and routine to the ordinary artisan. Given the specific primers taught by Weinberger for detecting the T131N or G130D mutation, the skilled artisan would have been realized that alternative primers would represent functional equivalents to amplify each of the mutations at positions 130, 131, 133 and 145, as taught by either Oon or Yoshida. The ordinary artisan would therefore have the alignment of Mbayed to facilitate designing of nucleic acid primers which would function to amplify nucleic acids flanking the T131N or G130D mutation.

Response to Arguments

The response traverses the rejection. The response asserts that the claims are not obvious in view of Weinberger and Mbayed because Mbayed does not teach or suggest using the primers of SEQ ID NO: 1 and 2 to detect HBV strains that may have

escaped immunological detection of HbaAg. This argument has been thoroughly reviewed, but is not found persuasive.

With respect to the Weinberger and Mbayed not specifically teaching SEQ ID NO: 1 and 2. The response previously argued (see arguments December 10, 2003) that "although SEQ ID NO: 1 shares some sequence identity with that of primer HBS, none of these 2 primer pairs have the same sequence as that of SEQ ID NO: 1 and 2. It is noted that the instant rejection is made under 103 rather than 102. The examiner acknowledges the standard for prima facie case of obviousness as set forth by the response, page 10. This argument has been reviewed but is not convincing because the combination of the references would have suggested all of the claimed limitations, would have provided suggestion to combine the references and there would have been a reasonable expectation of success. The response argues that Weinberger's teaching of numerous regions which are conserved among 30 isolates would not suggest that primer pairs may be modified to have SEQ ID NO: 1 and 2. Further the response argues that Mbayed's teachings of a primer pair that targets a different region of the HBV does not give "a clue as to how Weinberger's primer pairs should be modified to arrive at the claimed method." This argument has been thoroughly reviewed, but is not found persuasive because given the teachings in the art, the ordinary artisan would have targeted known conserved regions for amplifying the region containing the mutation at position 130, 131, 133 and 145. Unlike the response's characterization (in the response December 10, 2003), the primer pair of Mbayed is not to a different region. The forward primer of Mbayed is directed to the exact region targeted by SEQ ID NO: 1,

the forward primer. As noted in the rejection above, the HBS1 primer is 20 nucleotides in length. SEQ ID NO: 1 of the instant application comprises each of the 20 nucleotides of HBS1 with an additional T nucleotide on the 3' end. Further, the reverse primer of Mbayed is directed to a known conserved region, namely positions 694-713. As is clear from Weinberger, region 688-714 is a highly conserved region of the s-gene (Table 1, page 139). Therefore, both SEQ ID NO: 2 and the reverse primer of Mbayed are directed to conserved regions. SEQ ID NO: 2 is four base pairs upstream of the reverse primer taught by Mbayed. This does not constitute a "different region of the HBV." The ordinary artisan would have recognized that designing primers within highly conserved regions would be equivalents. Modifying primers such that the reverse primer is within a known conserved region would have yielded primers with the functionality of amplifying regions between the conserved primers.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologues, however, the court stated at page 1214:

> "Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologues because homologues often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties."

The examiner also notes that Deuel teaches at 1215, col. 1, No. 7, "Further, while the general idea of the claimed molecules, their function, and their general

chemical nature may have been obvious from Bohlen's teachings, and the knowledge that some gene existed may have been clear, the precise cDNA molecules of claims 5 and 7 would not have been obvious over the Bohlen reference because Bohlen teaches proteins, not the claimed or closely related cDNA molecules". In contrast, in the instant case, the very source of the claimed nucleic acid was provided. The reference even directs the attention to the very region the oligonucleotides are pulled from. Deuel did not find it obvious to probe a library to find full length DNA molecules given a smaller portion of the molecule. The instant case, however, is directed to a known full length molecule and determining smaller molecules which may function as probes and/or primers. Thus, the normal circumstances for a prima facie case should be followed as set out on 1214, col. 2. Weinberger and Mbayed teach the full length region of HBV with specific probes and primers within the nucleic acid.

The response filed December 10, 2003 further argues that a declaration has been filed by Dr. Chong Jin Oon. The response asserts that the declaration filed by Dr. Oon "demonstrates that the primer pair SE QID NO: 1 and 2 are superior to the primer pair MD14/HD03" (page 6 of response filed December 10, 2003). The declaration filed by Dr. Oon has been thoroughly considered, however is not deemed persuasive.

First, the MPEP provides in 716.02(e) a requirement of Comparison With Closest Prior Art. The MPEP states, "An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). "A comparison of the claimed invention with the disclosure of each cited

reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." In re Merchant, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained, In re Finley, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. In re Armstrong, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential). Applicant does not appear to have compared SEQ ID NO: 1 and 2 to the closest prior art, namely Mbayed (primer HBS1 nad HBS2. The oligonucleotide HBS1 overlaps SEQ ID NO: 1, namely 20/21 nucleotides of SEQ ID NO: 1. The oligonucleotides HBS2 of Mbayed is within the same conserved region as SEQ ID NO: 2 and is 4 base pairs downstream of SEQ ID NO: 2. Applicant has compared SEQ ID NO: 1 and 2 of the instant application to primers directed to nucleotides 418-433 and 734-748. Most importantly, a forward primer directed to positions 418-433 is not the closest prior art to a primer which overlaps 20/21 nucleotides of SE ID NO: 1, namely HBS1 (postions 455-474). The compared primer is also downstream of the claimed primer and does not overlap with the claimed primer in any way. A reverse primer directed to postions 734-748 is not the closes prior art to SEQ ID NO: 2. Mbayed teaches a primer directed to positions 694-713 which is within the same conserved region as taught by Weinberger, namley conserved positions 688-714. There is no teaching in the art to suggest that 734-748 is

a conserved region. Applicant does not appear to have compared SEQ ID NO: 1 and 2 to the closest prior art, namely Mbayed (primers HBS1 and HBS2).

Moreover, MPEP 716.02(d), provides that the unexpected Results must be Commensurate in Scope With Claimed Invention. Applicant has provided an analysis of primers consisting of SEQ ID NO: 1 and 2. The claims are drawn to primers having SEQ ID NO: 1 and 2. Having is open claim language which allows for additional sequences on either end of SEQ ID NO: 1 and 2. As written the claims would encompass a primer which comprises HBS2 and SEQ ID NO: 2. Using this primer, the specificity of the primer to the region would be identical to the results obtained in the art and would not be unobvious. The claims are not drawn to primers consisting of SEQ ID NO: 1-2, thus the results are not commensurate in scope with the nucleic acid sequences.

With respect to the instant arguments drawn to the references not teaching that the references teach detection of HBV strains through detection of a mutation in amino acid positions 130, 131, 133 and 145 of HbsAg, the newly added references, Oon or Yoshida specifically detect multiple mutations which have escaped immunological detection. The newly applied references are specifically directed to examining the 'a' determinant region for mutants which have escaped immunological detection. Oon or Yoshida each teach a combination of mutations which were found in strains which escaped immunological detection. Therefore, the ordinary artisan would have been motivated to have detected the combination of mutations within the known variable

region for any and all of the mutations known to be associated with escape from immunological detection.

Thus for the reasons above and those already of record, the rejection is maintained.

8. Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger et al. (Viral Hepatitis and Liver Disease, pages 138-143, Torino, Edizioni Minerva Medica, 1997) in view of Mbayed et al. (J. Clinical Microbiology, Vol. 36, No. 11, pages 3362-3365, November 1998) and further in view of either Yoshida et al. (Liver, Vol. 20, pages 411-414, October 2000) or Oon et al. (Antiviral Research, Vol. 41, pages 113-118, April 1999) as applied to Claims 22, 24-31 above, and further in view of Mason et al. (Hepatology, Vol. 27 (6) 1736-42, June 1998).

Neither Weinberger nor Mbayed nor Oon or Yoshida specifically teach reverse transcribing mRNA into cDNA prior to analysis.

However, Mason et al. (herein referred to as Mason) teaches hepatic nucleic acid extracts were assessed by PCR for either reverse-transcribed HBV RNA.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the methods of Weinberger in view of Mbayed and Oon or Yoshida with the teachings of Mason for reverse transcribing the HBV RNA prior to analysis to obtain DNA. The ordinary artisan would have been motivated to have reverse transcribed the HBV RNA into cDNA for the expected benefit of obtaining DNA which is more stable than RNA. Mason teaches that the reverse transcribed cDNA may be further analyzed by PCR.

Response to Arguments

The response traverses the rejection. The response asserts that Claim 22 as amended specifies a method for detecting a HBV strain that may have escaped immunological detection of HbsAG through detection of a mutation in amino acid positions 130, 131, 133 and 145. This argument has been reviewed but is not convincing because, as explained above, designing primers to known conserved regions which contain known mutations which are associated with escaped from immunological detection would have been obvious in view of the level of skill in the art at the time the invention was made. Mason has been used to teach that a sample may be first reverse-transcribed prior to PCR. Thus for the reasons above and those already of record, the rejection is maintained.

9. Claims 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weinberger et al. (Viral Hepatitis and Liver Disease, pages 138-143, Torino, Edizioni Minerva Medica, 1997) in view of Mbayed et al. (J. Clinical Microbiology, Vol. 36, No. 11, pages 3362-3365, November 1998) and further in view of either Yoshida et al. (Liver, Vol. 20, pages 411-414, October 2000) or Oon et al. (Antiviral Research, Vol. 41, pages 113-118, April 1999) as applied to Claims 22, 24-31 above and further in view of Dattagupta (EP 0 374 665, June 27, 1990).

Neither Weinberger nor Mbayed nor Oon or Yoshida specifically teaches the use of a labeled primer or a primer attached to a solid support in combination with a primer in solution.

However, Dattagupta specifically teaches a method for amplifying and detecting specific target nucleic acid sequences in a sample by contacting a first primer and a second primer with nucleic acid where one primer is immobilized and the other primer is labeled (Table 1, embodiments (3) and (6); page 4)(limitations of Claims 6-7). Dattagupta teaches that embodiments (3) and (6) of Table 1 may be assayed for using detection of the label on the support to determine the presence of the test amplified nucleic acid; by hybridization with a specific probe; extent of incorporation of a labeled nucleic acid residue; or a post extension agglutination reaction (page 4, lines 36-43). Dattagupta teaches that in an "immobilizable/labeled system, the biotin would be present on one primer and a label such as fluorescein would be on the second primer, following amplification by thermocycling, the biotin containing product could be immobilized" (page 7, lines 12-16)(limitations of Claim 5). Dattagupta provides that the improvement of the method over the Mullis patent is at least one of the primers is immobilized (page 3, line 34-35). Additionally, Dattagupta teaches that the PCR method is significantly improved by the use of immobilized or immobilizable nucleic acid primers. The final amplified products are already immobilized or specifically immobilizable without significant loss in efficiency of amplification (page 5, lines 9-12).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the PCR methods of Weinberger with the teachings of Dattagupta of the improvements of immobilization for detection of PCR products. The ordinary artisan would have been motivated to have immobilized and labeled the primers of Weinberger for the express benefits taught by Dattagupta. Dattagupta teaches that the

"PCR method is significantly improved by the use of immobilized or immobilizable nucleic acid primers. The final amplified products are already immobilized or specifically immobilizable without significant loss in efficiency of amplification." Therefore, the ordinary artisan would have been motivated to have immobilized and labeled the primers in the HBV detection methods for the express benefit of improved detection.

Conclusion

10. No claims allowable over the art.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272- 0745.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

J. Goldberg

Jeanine Goldberg
Patent Examiner
December 28, 2004